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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,350	04/18/2001	Robert M. Scribner	1759.15103-CON	1121

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EXAMINER

KOKABI, AZADEH

ART UNIT PAPER NUMBER

3751

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,350

Applicant(s)

SCRIBNER ET AL.

Examiner

Azy Kokabi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120


- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Priority

1. The benefit claim filed on 03/10/03 was not entered because the required reference was not filed prior to the later of four months from the filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(5). If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) a surcharge under 37 CFR 1.17(t); and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

 2. The transmittal filed on 04/18/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/088,459 is acceptable and will obtain a benefit date of June 1, 1998.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 80-82, 84-88, and 90-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Reiley et al (WO 95/20362).

In regard to claim 1, Reiley discloses an inflatable device with a flexible, resistant wall (pg. 6, lines 31-35 and pg. 7, lines 1-5), with an interior space (figure 6, # 88), having a proximal end (figure 17(a), #162) and a distal end (figure 17(a), #159). Reiley also discloses an expandable region with its cross-sectional area adjacent the proximal end (figure 18, #166) and a second expandable area with its cross-sectional area adjacent the distal end (figure 18, #170). The device also contains a third section with its interior cross sectional area located between the first and second expandable regions (figure 18, # 172). Reiley discloses that the third section has less interior cross sectional area than the interior cross sectional area of either the first or second expanded sections (figure 18). Reiley also discloses that the third section is surrounded by a mesh, therefore providing for a thicker wall than either the first or second expandable regions (pg. 9, lines 26-35 and pg. 10, lines 1-3 and figure 18, # 170). Reiley teaches that the expandable regions are predetermined (page 6, line 21) and further that the balloons are formed by molding (page 26, line 7).

In regard to claim 81, page 11, lines 4-17 disclose that the inflated balloons have restraints that will create flat surfaces, which will result in a diameter less than a sphere

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expanded to an equal inflation volume of the balloon. In regard to claim 82, Reiley discloses a balloon that expands outside the bone, having a diameter greater than the normally expanded shape. The balloons occupy 70-90% of the inner volume of the bone so that undue pressure is not exerted on the vertebral body (pg. 11, lines 31-34).

In regard to claim 84, Reiley discloses an expandable region that is “essentially” cylindrical. (See figure 4). In regard to claim 85, see figure 2. In reference to claim 86, Reiley discloses an expandable region that is in an “essentially” cylindrical manner (figure 4 and pg. 8, lines 34-35).

In regard to claim 87, Reiley sets forth the limitations as stated supra in claim 80. When rotating the device 180 degrees, the first balloon will be adjacent the distal end and the second expandable region will be adjacent the proximate end (see figure 18).

In regard to claim 88, figure 18 shows that the first expandable region surrounds the maximum cross sectional area of the first interior space and the second region surrounds the second maximum cross-sectional region of the interior space. Figure 18 also discloses that the expandable regions of the first and second expandable region are larger than the third expandable region.

In reference to claim 90, Reiley discloses all the limitations as set forth supra in claim 81 and 87. In addition, Reiley shows that the diameter of the third region is smaller than the average of the first and the second expandable regions. (See figure 18). In regard to claim 91, Reiley discloses of a flowable material that sets to a hardened condition in the interior wall (pg. 19, line 30).

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 83 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (WO 95/20362) in view of Reiley et al (WO 98/56301).

As previously, discussed in paragraph 4 above, further Reiley (WO 95/20362) discloses all the limitations as set forth, however Reiley (WO 95/20362) does not teach that the expandable region inside the bone corresponds to the expanded shape outside the bone.

Reiley (WO 98/56301) discloses a balloon inside the bone that corresponds to the shape of a balloon outside the bone (Compare figure 37 A and B). It would have been obvious to one of ordinary skill in the art to modify the device of Reiley (WO 95/20362) with an expandable region inside the bone that corresponds to the expandable region outside the bone, in order to provide confidence for the physician by allowing him to select a structure in an open-air environment.

7. In reference to claim 89, Reiley (WO 95/20362) does not disclose of a wall made of polyurethane. Reiley (WO 98/56301), however, discloses that the wall of the inflatable device comprises of polyurethane for expansion of the expandable member.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Reiley (WO 95/20362) with a wall made of polyurethane in order to provide a durable and flexible material to be inflated inside the cancellous bone.

8 In reference to new claims 92-94, Reiley does not specify the mode of manufacture of the catheter balloons, however the "Prior Technique for the Manufacture of Balloon" section of the reference refers to patent number 5,163,989 by Campbell, which discloses a molding process of making balloons (see page 3 and 4 of Reiley reference)

Campbell discloses a mold and technique for molding dilation catheters in which the balloons of the catheter is free of parting lines. The technique involves inflating a plastic member of tubular shape so as to press it against the inner molding surface, which is heated. Inflatable devices are molded into the desired size and shape, then cooled and deflated to remove it from the mold. This process is used to obtain a variety of balloons, with different sizes and shapes.

Therefore, it would have been obvious to specify the manufacture of balloons for in patient use in order to form a wide variety of balloons of different sizes and shapes.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sawhney et al, Gottschalk, Bonutti, and Durcan et al are cited as general inflatable device.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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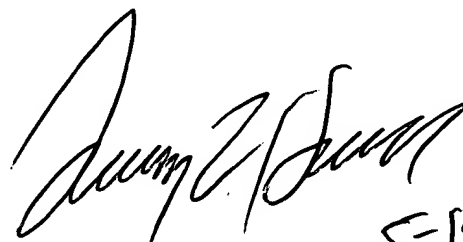
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3588 for regular communications and (703) 305-3588 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

AK
May 19, 2003



5-19-03

GREGORY HUSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700